

## **ISPAGEL**

### **SCHEDULING STATUS:**

S0

### **PROPRIETARY NAME AND DOSAGE FORM:**

**ISPAGEL** granules

### **COMPOSITION:**

Each sachet contains 3,5 g Ispaghula husk.

### **PHARMACOLOGICAL CLASSIFICATION:**

A 11.5 Laxatives. Medicines acting on gastro-intestinal tract.

### **PHARMACOLOGICAL ACTION:**

Ispaghula husk is a bulk forming laxative. Ispaghula husk absorbs water in the gastrointestinal tract to form a mucilaginous mass which increases the volume of the faeces and hence promotes peristalsis.

### **INDICATIONS:**

**ISPAGEL** is recommended for the treatment of patients requiring a high-fibre regimen, for constipation and for those requiring normalisation of faecal consistency as in irritable bowel syndrome and diverticular disease.

### **CONTRA-INDICATIONS:**

**ISPAGEL** is contra-indicated in patients on a salt restricted diet. Bulking agents such as **ISPAGEL** should not be given to patients with symptoms of appendicitis, obstruction, abdominal pain of unknown cause, patients who have difficulty swallowing, patients with pre-existing faecal impaction or colon atony.

### **WARNINGS:**

Persistent constipation should be investigated. The habitual use of **ISPAGEL** and other laxatives should be avoided.

**INTERACTIONS:**

There is a possibility that **ISPAGEL** may reduce or delay gastrointestinal absorption of other medicines given concomitantly.

**PREGNANCY AND LACTATION:**

**ISPAGEL** may be used during pregnancy and lactation at the recommended dosage.

**DOSAGE AND DIRECTIONS FOR USE:**

Adults and children over 12: One sachet (3,5 g ispaghula) morning and evening.

Children 6 to 12 years: As directed by the medical practitioner depending on then child's age and size.

**ISPAGEL** should be stirred into at least 150 ml water and taken as soon as possible, preferably after meals.

**SIDE EFFECTS AND SPECIAL PRECAUTIONS:****Side Effects:****Immune system disorders**

*The following side effects have been reported but frequencies are unknown:*

Allergies to some vegetable components; hypersensitivity to ispaghula.

**Gastrointestinal system disorders**

*The following side effects have been reported but frequencies are unknown:*

Oesophageal blockage or intestinal impaction; increased flatulence and abdominal distention.

**Special precautions:**

**ISPAGEL** should always be taken with sufficient fluid and should not be taken immediately before going to bed.

**KNOWN SYMPTOMS OF OVERDOSAGE AND PARTICULARS OF ITS TREATMENT:**

In the event of overdosage, conservative measures should be taken. The patient may notice abdominal discomfort and flatulence and attention should be paid to maintaining an adequate fluid intake, particularly if the granules have been taken without water, contrary to the administration instructions.

**IDENTIFICATION:**

Beige, yellowish colour powder with a characteristic odour.

**PRESENTATION:**

30 white coloured thick paper/aluminium/polyethylene sachets in a white outer carton.

**STORAGE INSTRUCTIONS:**

Store below 25°C in a dry place.

KEEP OUT OF REACH OF CHILDREN.

**REGISTRATION NUMBER:**

39/11.5/0115

**NAME AND BUSINESS ADDRESS OF THE HOLDER OF THE CERTIFICATE OF REGISTRATION:**

Pharma Dynamics (Pty) Ltd

F02 Grapevine House

Steenberg Office Park

Westlake

7945

**DATE OF PUBLICATION OF THE PACKAGE INSERT:**

18 July 2006

## ISPAGEL

### SKEDULERINGSSTATUS:

S0

### EIENDOMSNAAM EN DOSEERVORM:

**ISPAGEL** granules

### SAMESTELLING:

Elke sakkie bevat 3,5 g Ispagula doppe (of skil)

### FARMAKOLOGIESE KLASSIFISERING:

A: 11.5 Lakseermiddels. Middels met uitwerking op maagdermkanaal.

### FARMAKOLOGIESE WERKING:

Ispagulaskil is 'n massa-vormende lakseermiddel. Ispagulaskil absorbeer water in die spysverteringskanaal om 'n klewerige massa te vorm wat die volume van die stoelgang verhoog en dus peristalse bevorder.

### INDIKASIES:

**ISPAGEL** word aanbeveel vir die behandeling van pasiënte wat 'n hoë-vesel-regimen nodig het, vir hardlywigheid en vir dié wat normalisering van stoelgangdigtheid soos in prikkelbare derm sindroom en divertikulêre siekte benodig.

### KONTRA-INDIKASIES:

**ISPAGEL** is teenaangedui in pasiënte op 'n sout-beperkte dieet. Massa-vormende middels soos **ISPAGEL** moet nie vir pasiënte met simptome van blindedermonsteking, obstruksie, abdominale pyn van onbekende oorsprong, pasiënte wat probleme met sluk ondervind, of pasiënte met voorafbestaande fekale impaksie of atonie van die kolon, toegedien word nie.

### WAARSKUWINGS:

Aanhoudende hardlywigheid moet ondersoek word. Die gedurige gebruik van **ISPAGEL** en ander lakseermiddels moet vermy word.

## **INTERAKSIES:**

Die moontlikheid bestaan dat **ISPAGEL** gastroïntestinale absorpsie van ander medisyne wat gelyktydig gegee word, mag verminder of vertraag.

## **SWANGERSKAP EN LAKTASIE:**

**ISPAGEL** mag tydens swangerskap en laktasie teen die aanbevole dosering gebruik word.

## **DOSERING EN GEBRUIKSAANWYSINGS:**

Volwassenes en kinders ouer as 12: Een sakkie (3,5g ispagula) soggens en saans.

Kinders van 6 tot 12 jaar: Soos deur 'n geneesheer voorgeskryf afhangende van die ouderdom en grootte van die kind.

**ISPAGEL** moet in ten minste 150 ml water geroer word en so vinnig as moontlik, liefs na maaltye, geneem word.

## **NEWE-EFFEKTE EN SPESIALE VOORSORGMAATREËLS:**

### **Neuwe-effekte:**

#### **Immuunsisteemversteurings**

*Die volgende neue-effekte is aangemeld, maar hulle frekwensies is onbekend:*

Allergieë teenoor sommige plantkomponente; hipersensitiwiteit teenoor ispagula.

#### **Spysverteringskanaalversteurings:**

*Die volgende neue-effekte is aangemeld, maar hulle frekwensies is onbekend:*

Esofageale blokkering of intestinale impaksie; verhoogde winderigheid en abdominale uitsetting.

#### **Spesiale voorsorgmaatreëls:**

**ISPAGEL** moet altyd met voldoende vloeistof geneem word en behoort nie onmiddellik voor slapenstyd geneem te word nie.

## **BEKENDE SIMPTOME VAN OORDOSERING EN BESONDERHEDE VAN DIE BEHANDELING DAARVAN:**

In geval van oordosering, moet konserwatiewe maatreëls toegepas word. Die pasiënt mag abdominale ongemak en winderigheid ervaar, en aandag moet gegee word om 'n toereikende vloeistofinname te onderhou, veral as die granules sonder water, teenstrydig met die gebruiksaanwysings, geneem is.

**IDENTIFIKASIE:**

Beige, gelerige poeier met 'n kenmerkende geur.

**AANBIEDING:**

30 witgekleurde, dik papier/aluminium/poliëtileen sakkies in 'n wit buitenste karton.

**BERGINGSINSTRUKSIES**

Bewaar benede 25 °C in 'n droë plek.

HOU BUITE BEREIK VAN KINDERS.

**REGISTRASIENOMMER**

39/11.5/0115

**NAAM EN BESIGHEIDSADRES VAN DIE HOUER VAN DIE  
REGISTRASIESERTIFIKAAT**

Pharma Dynamics (Edms) Bpk.

F02 Grapevine House

Steenberg Office Park

Westlake

7945

**DATUM VAN PUBLIKASIE VAN HIERDIE VOUBILJET**

18 Julie 2006